



Complete Summary

GUIDELINE TITLE

Peptic ulcer disease.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. UMHS peptic ulcer guideline. Ann Arbor (MI): University of Michigan Health System; 1999 May. 6 p. [7 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Peptic ulcer disease (PUD)
- Helicobacter pylori infection (HP)

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To implement a cost effective strategy incorporating testing for and eradication of *Helicobacter pylori* in patients with suspected peptic ulcer disease.
- To reduce ulcer recurrence and prevent the overuse of chronic anti-secretory medications in peptic ulcer disease patients.

TARGET POPULATION

Adults with peptic ulcer disease

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis of *H. pylori* (HP) infection

1. Non-invasive HP tests, such as antibody testing and tests for active HP (fecal HP antigen testing; urea breath testing)
2. Diagnostic endoscopy

Treatment

1. Proton pump inhibitor based triple therapies (PPIs):
 - PPIs Lansoprazole or Omeprazole, Amoxicillin, and Clarithromycin
 - The three packaged together: Prevpac® (using PPI Lansoprazole)
 - PPIs Lansoprazole or Omeprazole, Metronidazole, and Clarithromycin or Amoxicillin
2. "Conventional Triple Therapy" for *H. pylori*:
 - Bismuth (Peptobismol), metronidazole, and tetracycline or amoxicillin, combined with an H2 blocker (Cimetidine, Famotidine, Nizatidine or Ranitidine) or a Proton Pump Inhibitor (Lansoprazole or Omeprazole)
 - The three packaged together: Helidac® combined with an H2 blocker (Cimetidine, Famotidine, Nizatidine or Ranitidine) or a Proton Pump Inhibitor (Lansoprazole or Omeprazole)

Note: dual therapy of single PPI and a single antibiotic is not recommended.

Referral for further evaluation (gastroenterology)

MAJOR OUTCOMES CONSIDERED

- Symptomatic relief
- Relative effectiveness of anti-*H. pylori* (HP) therapies
- Assessment of diagnostic tests (sensitivity, specificity, predictive value, accuracy)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search for this project was conducted prospectively using the major keywords of: "peptic ulcer" and "H. pylori," "dyspepsia" and "H. pylori," "guidelines," "controlled trials," adults, published from 1986 to 1995. An updated search added publications from 1996 through September 1998. All searches were performed using MEDLINE (U.S. National Library of Medicine). Terms used for specific treatment topic searches within the major key words included: history, serologic testing, endoscopy, other references to diagnosis, antibiotics, antisecretory drugs, other references to treatment, and other references not included in the previous specific topics. The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with very recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The search was a single cycle.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of evidence for the most significant recommendations:

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials (RCTs), if available, to the exclusion of other data; if RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Published cost-effectiveness studies were reviewed. One study was an economic analysis that supported the role for initial serology-based treatment of *Helicobacter pylori* infection (HP) in patients with suspected ulcer disease.

Another analysis estimated the prevalence of HP in a population necessary for wide spread screening to be cost-effective in preventing gastric cancer.

Finally, a large study was reviewed that demonstrated the effect and cost savings of initial serology-based treatment of HP in patients with suspected ulcer disease.

For more details, refer to the Annotated References section of the original guideline document.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership in departments to which the content is most relevant. This guideline concerning peptic ulcer disease was reviewed by members of the following departments: Gastroenterology; General Medicine; Family Medicine.

Guidelines are approved by the Primary Care Executive Committee (PCEC) and the Executive Committee of Clinical Affairs (ECCA).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing and cost considerations for therapy for *Helicobacter pylori* (*H. pylori* [HP])) associated peptic ulcer disease (PUD).

- Clinical approach.

Nine out of ten ulcers are caused by an infection of a bacterium known as *Helicobacter pylori* (HP). Eradication of HP infection alters the natural history of peptic ulcer disease. Successful eradication reduces PUD recurrence rate

from 90% to about 20% per year [A*]. PUD generally does not recur in the successfully treated patient unless nonsteroidal anti-inflammatory drug (NSAID) use is present.

- Diagnosis.

Economic analyses demonstrate a cost effectiveness advantage of non-invasive testing and antibiotic therapy for HP in patients with symptoms suggestive of PUD when compared to immediate endoscopy. [C]*

- Treatment.

HP eradication therapy consists of antibiotics and antisecretory drugs. [A*]
Long-term acid inhibition is inappropriate in the management of HP-related PUD in most instances. [B*]

- Follow-up.

Referral to the gastroenterologist should occur for all patients with signs and symptoms of complicated ulcer disease and for patients who fail initial therapy based on a non-invasive test. Persistent symptoms after 2 weeks of therapy suggests an alternative diagnosis.

*Definitions

Levels of evidence for the most significant recommendations:

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Decision analysis
- D. Opinion of expert panel

CLINICAL ALGORITHM(S)

An algorithm is provided for the management of peptic ulcer disease.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for the most significant recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Cost-effective approach to diagnosis: Serologic testing for *Helicobacter pylori* (HP) is very accurate and the least expensive method for office diagnosis of infection in untreated patients.
- Economic analyses demonstrate a cost effectiveness advantage of non-invasive testing and antibiotic therapy for HP in patients with symptoms suggestive of peptic ulcer disease (PUD) when compared to immediate endoscopy.
- Effective treatment: Successful eradication of HP infection reduces PUD recurrence rate from 90% to about 20% per year.

Subgroups Most Likely to Benefit:

Testing for active infection (fecal *Helicobacter pylori* (HP) antigen testing; urea breath testing) may be more cost-effective in populations likely to have been previously treated successfully.

POTENTIAL HARMS

- The clinical approach involving initial serologic testing for *Helicobacter pylori* (HP) and antibiotic therapy for those patients who test positive for HP infection is associated with the risk of overtreating those patients who are infected with HP (or those with a false positive serology) but do not have active ulcer disease.
- Antibody tests do not differentiate between previously eradicated HP and currently active HP.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. UMHS peptic ulcer guideline. Ann Arbor (MI): University of Michigan Health System; 1999 May. 6 p. [7 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Oct (revised 1999 May)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

Internal funding for University of Michigan Health System (UMHS) guidelines is provided by the Office of Clinical Affairs. No external funds are used.

GUIDELINE COMMITTEE

Peptic Ulcer Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members: A. Mark Fendrick, M.D.; Van Harrison, Ph.D.; Ray Rion, M.D.; James Scheiman, M.D.; Connie Standiford, M.D.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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GUIDELINE STATUS

This is the current release of the guideline. It is an update of a previously issued guideline (Peptic ulcer disease. Ann Arbor [MI]: University of Michigan Health System; 1996).

The next update is scheduled for 2002.

GUIDELINE AVAILABILITY

Electronic copies: Available for download (in Portable Document Format [PDF]) from the [University of Michigan Health System Web site](#). Continuing Medical Education (CME) information is [also available](#).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on August 21, 2000. The information was verified by the guideline developer on November 22, 2000.

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